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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,579	07/18/2000	SERGEY A. SELIFONOV	02-028950US	8517

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	18

DATE MAILED: 12/10/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/618,579	SELIFONOV ET AL.	
	Examiner	Art Unit	
	Shubo "Joe" Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-132* is/are pending in the application.

4a) Of the above claim(s) *1-92 and 106-132* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *93-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 July 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9-11,16-17*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment and request for reconsideration in Paper #15, filed on 9/27/01/01, is acknowledged and the amendments entered.

Applicant's arguments in response to the previous Office Action, mailed 4/24/01, along with the interview between the Examiner and applicant's representatives on 8/8/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections from previous Office actions not reiterated herein are hereby withdrawn. The following rejections and/or objections are either reiterated from the previous Office actions, or newly applied, and constitute the complete set presently being applied to the instant application.

Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement in the Office action mailed 4/24/01, applicant's election of Group IX (claims 93-105) has been treated as an election without traverse (MPEP § 818.03(a)).

The newly added claims 106-132 are not drawn to the inventions of the elected Group IX (claims 93-105). Claims 106-132 and the claims of Group IX are directed to distinct inventions. Claims 106-132 are directed to methods for making recombinant nucleic acids involving procedures such as providing oligonucleotides and annealing each other thereto, classified in Class 435, 91.52, while claims of Group IX are directed to methods of producing recombinant nucleic acids or polypeptides involving in silico procedures, classified in Class 702, subclass 19. These methods are distinct both

physically and functionally, require different process steps, reagents and parameters, and produce different products. Consequently, these inventions have acquired a separate status in the art as a separate subject for inventive effect and are usually published separately. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Thus, claims 106-132 are withdrawn from further consideration as being drawn to non-elected inventions.

Claims 1-132 are currently pending and only claims 93-105 are under examination.

This application contains claims 1-92, and 106-132, drawn to inventions non-elected in Paper No. 8. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Claim Rejections-35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 93-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jonsson et al. (Nucleic Acids Research, 1993, Vol. 21, No.3, pages 733-739).

This rejection is reiterated from the previous Office action and maintained for reasons of record.

Applicants argue that Jonsson et al. is unrelated to the claimed invention. This is not deemed persuasive because Jonsson used an in silico procedure to design and produce recombinant nucleic acids among 25 parental nucleic acid sequences, which is the subject matter of the elected Group IX, drawn to methods of producing recombinant nucleic acids involving in silico procedures, as set forth in the previous Office action. Clearly, Jonsson et al. is related to the instant invention.

Applicants also argue that "at no time, explicitly or inherently, were crossover sites between nucleic acids determined by Jonsson et al." This is not found persuasive because as clearly set forth in the previous Office action, "although Jonsson et al. do not explicitly use the term "recombination" or "recombinant" as required in the instant claims, it would have been obvious to one of ordinary skill in the art to have understood that the sequences predicted by the model, Pls1 and Pls2 , are recombinant sequences since they recombine all the sequences of positions in the 25 promoters that contribute most to the maximum overall promoter activity" (page 8, first paragraph). Obviously, recombination occurs, and recombination requires crossover sites. In order to select recombinant nucleic acids that have promoter activity higher than the parental nucleic acids, recombination is allowed to occur at every site and then computer models are

used for selection. Thus, the Jonsson et al. reference does inherently involve recombination and crossover sites.

Enclosed please find *inter alia* copies of the PTO-1449 forms with multiple references lined through because the references do not have a publication date. Although these references will not be listed on PTO-1449, they have been considered by the Examiner. However, the reference by Egea Biosciences, Inc. has not been considered.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL.

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory

action. In no event, however, will the statutory period for reply expire later than six

months from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is 703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.

Patent Examiner

MICHAEL BORIN, PH.D
PRIMARY EXAMINER